

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products  
Liability Litigation

No. MD-15-02641-PHX-DGC

**EXHIBIT INDEX**

**PLAINTIFFS' RESPONSE IN  
OPPOSITION TO DEFENDANTS'  
MOTION TO EXCLUDE THE OPINIONS  
OF DARREN R. HURST, M.D.**

Exhibit 1     Hurst CV

Exhibit 2     Hurst Deposition Excerpts 7-21-17

Exhibit 3     Tillman Deposition Excerpts 8-4-16

Exhibit 4     DeCant Deposition Excerpts 5-24-16

Exhibit 5     DeFord Deposition Excerpts 6-2-16 (**FILED UNDER SEAL**)

Exhibit 6     Ganser Deposition Excerpts 10-11-16 (**FILED UNDER SEAL**)

# **EXHIBIT 1**

(Filed Under Seal)

# EXHIBIT 2

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UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA

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IN RE BARD IVC )  
FILTERS PRODUCTS ) No. MD-15-02641-PHX-DGC  
LIABILITY LITIGATION )  
-----x

DO NOT DISCLOSE - SUBJECT TO FURTHER  
CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF DONNA-BEA TILLMAN, Ph.D.  
WASHINGTON, D.C.  
FRIDAY, AUGUST 4, 2017  
9:18 A.M.

Reported by: Leslie A. Todd

1           Q    Would you agree with me that -- that the  
2   risk-benefit analysis for purposes of using a  
3   medical device like a Bard filter should be  
4   something that physicians should have the ability  
5   to do in order to provide informed consent to  
6   their patients?

7           A    So at the risk of rephrasing your  
8   question, I think that physicians need to have  
9   enough information to understand the risks and the  
10   benefits in order to advise their patients.

11           Q    And to advise their patients pursuant to  
12   a physician's obligation to provide informed  
13   consent. Agreed?

14           A    And to provide informed consent.

15           Q    What does "fair and balanced" mean as a  
16   regulatory term?

17           A    Well, I would interpret it to mean that  
18   you present data that's both favorable and not  
19   favorable when you're trying to make a scientific  
20   argument.

21           Q    What are -- there's an issue here about  
22   monitoring, right, whether or not the labeling  
23   should have included monitoring. I think you  
24   comment on it. Dr. Kessler comments on it.

# EXHIBIT 3



# The NEW ENGLAND JOURNAL of MEDICINE

Perspective  
JUNE 1, 2006

## Life-Threatening Malfunction of Implantable Cardiac Devices

Robert J. Myerburg, M.D., David W. Feigal, Jr., M.D., M.P.H., and Bruce D. Lindsay, M.D.

During the summer of 2005, in the wake of widespread criticism of its failure to communicate the potentially fatal malfunctions of its implantable defibrillators,<sup>1,2</sup> Guidant Corporation created an

independent panel, of which we were members. The purpose of the panel was to conduct an unbiased examination of these incidents, including the methods used to identify the malfunctions and evaluate products in the post-marketing phase and the policies regarding communication within the corporation and with physicians and patients. The panel was also asked to recommend corrective actions. Concurrently, the Heart Rhythm Society—which represents physicians who implant cardiac devices—established a task force to examine assessments of device performance and develop policy recommendations and guidelines.<sup>3</sup> Since the report by

the independent panel had implications for the device industry in general, Guidant made it available to the public.<sup>4</sup>

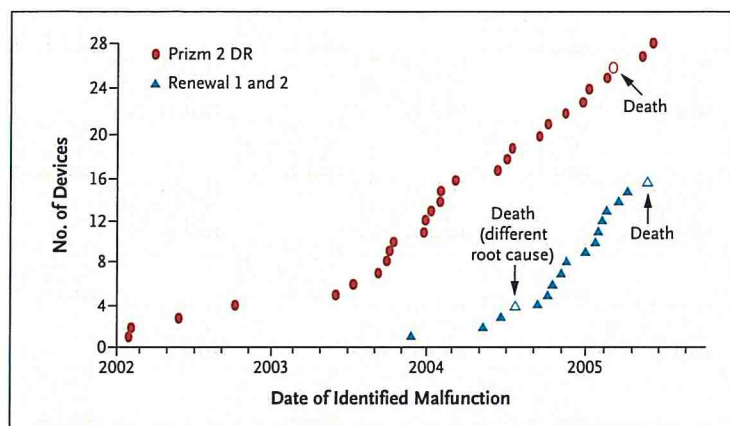
Three points quickly emerged as guidelines for the panel's deliberations. First, manufactured products can never be entirely free of design or manufacturing flaws, but when the consequence of a malfunction is a potentially fatal event, tolerance and surveillance strategies should aim to achieve a risk of malfunction that is as close to zero as possible. Second, physicians must know about the performance features of any device they recommend for a patient, so that they can carry out their ethical obligation of obtaining

informed consent. This information must be in a form that is understandable and clinically useful. And third, patients have a right to obtain product information so that they can make informed decisions about risks and benefits and can understand what expectations are reasonable.

The panel recognized that, as compared with the clinical benefit of implantable cardiac devices, the rate of serious malfunctions is very low. We also concluded, however, that if a malfunction is life-threatening, even a low risk of its occurrence takes on importance beyond its numbers. Although it is intuitively clear that any manufactured product will have a measurable failure rate, until recently, industry had not provided information to physicians about potentially serious malfunctions when the failure rates fell within the overall performance predic-







**Defects Leading to Potential Failure in Two Types of Guidant Implantable Defibrillators.**

The numbers of implantable defibrillators identified between 2002 and mid-2005 as having defects that predisposed them to short-circuiting (arcing), with an attendant risk of failure to deliver therapy when needed, are shown. The Prizm 2 DR was a conventional implantable defibrillator, and Renewal 1 and 2 were implantable defibrillators with biventricular pacing capability. Open symbols represent malfunctions that were associated with the death of a patient; one of these malfunctions was due to a random manufacturing defect rather than to the identified defect that resulted in short-circuiting ("different root cause"). Adapted from Myerburg et al.<sup>4</sup>

tions.<sup>4</sup> In most cases, these malfunctions were simply folded into overall statistics that also included less critical malfunctions and the expected depletion of batteries over time — a practice that made serious but infrequent malfunctions invisible to physicians and patients.

Although there is no industry-wide performance standard for malfunction rates in the cardiac-device industry, all companies are required by the Food and Drug Administration (FDA) to evaluate device malfunctions systematically in the post-marketing phase, to identify those that are clinically significant, to correct defects, and to act to prevent failures in performance. These internal processes necessarily center on engineering skills and methods. But the consequences of device malfunctions are more than an issue for engineering: they have clinical implications for patients that may include a risk of fatal events. Thus,

engineering performance standards are insufficient benchmarks without evaluation by experts of the possible effects on individual patients. The independent panel concluded that the lack of adequate clinical expertise, combined with undue reliance on arbitrary statistical criteria, led to decisions that had potentially and manifestly serious consequences. The graph shows the number of implantable defibrillators that were identified as having defects that predisposed them to short-circuiting (arcing) between 2002 and 2005.

As the number of defibrillators with life-threatening malfunctions continued to grow, the overall reliability of the products remained within the predicted rates. Therefore, in keeping with the company's standard practices at the time, the engineering group at Guidant decided, without any input from physicians, that it was unnecessary to inform physician-customers about these events.<sup>4</sup> In addition,

implantations of the potentially defective defibrillators continued for a time, and physicians, hospitals, and patients were not informed that the devices had flaws that could result in the inability to deliver therapy when necessary. It seems clear that the industry needs physicians with defined responsibilities focused on patient safety to provide recommendations to corporate leaders.

Post-marketing surveillance continues to be a challenge for the FDA and industry. Clinical trials rarely identify significant signals of very uncommon adverse events, and only a small proportion of later events are ever reported. One potential solution to this limitation of tracking, at least for cardiac devices, lies in the National Cardiovascular Data Registry mandated by the Centers for Medicare and Medicaid services for implantable cardioverter-defibrillators, which could be expanded and adapted to other databases. Moreover, the number of malfunctions that occur at the time of deaths that are assumed to be from natural causes remains unknown, because most devices are not returned to manufacturers for evaluation after patients die.

The FDA recently announced plans to address post-marketing surveillance more actively, including having electrophysiology experts from its Circulatory System Devices Panel review the post-marketing performance of implantable devices. The Heart Rhythm Society's task force also suggested that the FDA establish post-marketing advisory committees to recommend actions that should be taken when malfunctions are identified in defibrillators or pacemakers.<sup>5</sup> These steps could help the FDA address many issues, in-



cluding the lack of standard definitions and classifications of malfunctions that makes evaluating reports from different manufacturers problematic. It is uncertain whether the FDA could appreciably enhance the effectiveness of its post-marketing surveillance program without expanding both its authority and its budget. But if patient safety is a priority, the federal government should appropriate the funds required to make this effort feasible, without adversely influencing the FDA's other areas of responsibility.

In the meantime, companies must reevaluate their approach to patient safety in the context of communication. A critical question is when and how information about product performance should be communicated to physicians and patients. Although the issues — both ethical and practical — are complex, one conclusion is clear: transparency in matters that affect patient safety should be embraced as a primary corporate obligation.

In the past, this industry has not had a good record of open communication, but transparency does benefit companies that want to be viewed as trusted partners in the health care enterprise. As the panel noted, transparency may be passive, with information made available to those who seek it; active, with information targeted to specific groups of stakeholders; or forced, with a third party bringing forth information that elicits further disclosure by a company, as a defensive move. From the perspective of physicians' and patients' expectations, corporate responsibility, and public perception, we believe that proactive communication policies,

centering on the proper use of active and passive transparency, should be the norm. Insofar as such communication is hindered by perceived business conflicts, the solution may lie in new regulatory definitions that distinguish informational actions from those that indicate the removal of a device. Changing language can be difficult, since much of it is embedded in statutory requirements.

The panel also recommended that Guidant establish an independent review group to provide unbiased analysis of information on product performance and advice on decisions about external communications. Voluntary, independent review at the level suggested is a notion both foreign and frightening to most corporations, whose perceived need is to protect business interests. But corporate culture fosters a loyalty to corporate goals that may create unintended bias and distorted perceptions about product performance and patient safety. Independent review groups could assist corporations by generating unbiased advice that was responsive to society's view of the best business practices and clinical priorities.

Historically, corporations have — by themselves — set the expectations for device reliability and the communication of product malfunctions, seeking little input from patients, physicians, or professional organizations. This practice developed in the early years of the industry, when the combination of small numbers of device recipients and low malfunction rates made it difficult to detect problems. With the explosive growth of the industry in

recent years, previously unrecognized signals have become increasingly visible. Clearly, strategies for evaluating and communicating device malfunctions must be adjusted accordingly. Our conclusion is that industry should work collaboratively with physicians, professional societies, patient representatives, and regulatory agencies to establish reasonable standards and guidelines for the device industry to follow. Patients deserve nothing less.

The opinions expressed in this article reflect the views of the authors and are not endorsed by Guidant or any of the institutions or organizations with which the authors are affiliated.

Drs. Myerburg, Feigal, and Lindsay report having received honoraria from Guidant. Dr. Myerburg also reports having received consulting fees from Procter & Gamble and Reliant and having served as an expert witness. Dr. Lindsay reports having received consulting fees from Medtronic.

This article was published at [www.nejm.org](http://www.nejm.org) on May 15, 2006.

Dr. Myerburg is a professor of medicine and physiology at the University of Miami Miller School of Medicine, Miami. Dr. Feigal is a partner at NDA Partners, Phoenix, Ariz., and the former director of the Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Md. Dr. Lindsay is an associate professor of medicine and director of cardiac electrophysiology at Washington University School of Medicine, St. Louis.

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4. Myerburg RJ, Apostolakis GE, Beller GA, et al. Report of the Independent Panel of Guidant Corporation. March 20, 2006. (Accessed May 11, 2006, at <http://www.guidant.com/panel/panel.pdf>.)
5. Heart Rhythm Society Task Force report on device performance policies and guidelines. *Heart Rhythm* (in press).

# EXHIBIT 4

# Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type

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Semin Intervent Radiol 2016;33:93–100

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## Abstract

Many inferior vena cava (IVC) filter types, along with their specific risks and complications, are not recognized. The purpose of this study was to evaluate the various FDA-approved IVC filter types to determine device-specific risks, as a way to help identify patients who may benefit from ongoing follow-up versus prompt filter retrieval. An evidence-based electronic search (FDA Premarket Notification, MEDLINE, FDA MAUDE) was performed to identify all IVC filter types and device-specific complications from 1980 to 2014. Twenty-three IVC filter types (14 retrievable, 9 permanent) were identified. The devices were categorized as follows: conical ( $n = 14$ ), conical with umbrella ( $n = 1$ ), conical with cylindrical element ( $n = 2$ ), biconical with cylindrical element ( $n = 2$ ), helical ( $n = 1$ ), spiral ( $n = 1$ ), and complex ( $n = 1$ ). Purely conical filters were associated with the highest reported risks of penetration (90–100%). Filters with cylindrical or umbrella elements were associated with the highest reported risk of IVC thrombosis (30–50%). Conical Bard filters were associated with the highest reported risks of fracture (40%). The various FDA-approved IVC filter types were evaluated for device-specific complications based on best current evidence. This information can be used to guide and optimize clinical management in patients with indwelling IVC filters.

## Keywords

- IVC filters
- nonthrombotic complications
- interventional radiology

**CME Objective:** Upon completion of this article, the reader should be able to distinguish the various retrievable and permanent IVC filter designs, and explain the most common complications associated with the various designs.

**Accreditation:** This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Tufts University School of Medicine (TUSM) and Thieme Medical Publishers, New York. TUSM is accredited by the ACCME to provide continuing medical education for physicians.

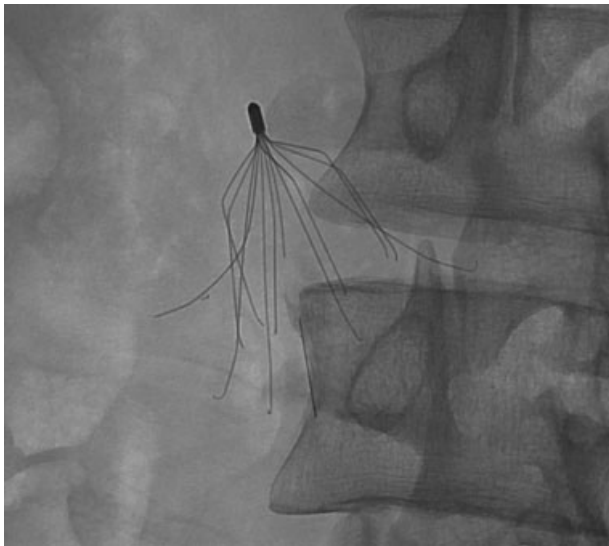
**Credit:** Tufts University School of Medicine designates this journal-based CME activity for a maximum of **1 AMA PRA Category 1 Credit™**. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The use of inferior vena cava (IVC) filters has dramatically increased over the past three decades in the United States, and the number of filter insertions doubled between 1998 and 2008.<sup>1,2</sup> By 2012, an estimated 259,000 IVC filters were placed in the United States alone,<sup>3</sup> coinciding with a growing number of Food and Drug Administration (FDA)-approved devices. Consequently, the increasing variety of filters along with rising overall use has resulted in increased complications from indwelling IVC filters; this prompted the FDA to issue a safety alert urging all physicians caring for patients with indwelling filters to consider removing the filter as soon as protection from pulmonary embolism (PE) is no longer needed.<sup>4</sup> Despite this recommendation, many devices are not adequately followed for removal, and the large number of filter types now encountered on routine imaging has made proper device identification difficult. The purpose of this study was to evaluate the various FDA-approved IVC filter designs to determine device-specific risks, as a way of

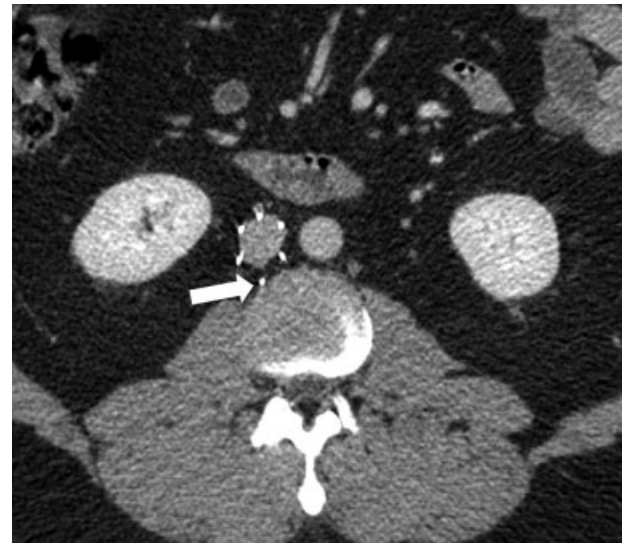
Issue Theme Inferior Vena Cava Filters;  
Guest Editors, Kush R. Desai, MD, and  
Robert J. Lewandowski, MD

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ISSN 0739-9529.



**Fig. 1** Fluoroscopic image showing a G2 filter with multiple fractured components.



**Fig. 3** Axial CT image showing a 12F Stainless Steel Greenfield filter in place complicated by component perforation (arrow).

helping to identify patients who may benefit from ongoing follow-up or prompt filter retrieval.

## Materials and Methods

### Identification of IVC Filter Types

The FDA Premarket Notification Database<sup>5</sup> was searched electronically to identify all IVC filters receiving 510(k) clearance (product code DTK—filter, intravascular, cardiovascular) between 1980 and 2014.

### Classification of Filter Complications

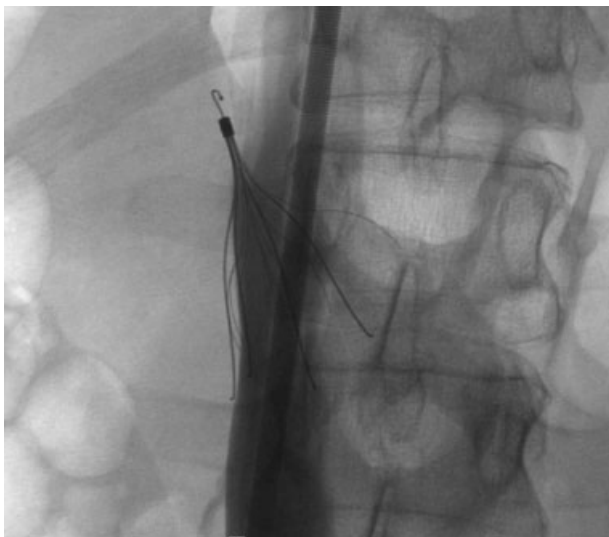
IVC filter complications were classified according to the Society of Interventional Radiology (SIR) guidelines<sup>6</sup> as follows:

**Fracture:** Breakage or separation of any filter component due to structural failure.<sup>6</sup> The fractured components can remain in situ or undergo distal embolization (► **Fig. 1**).

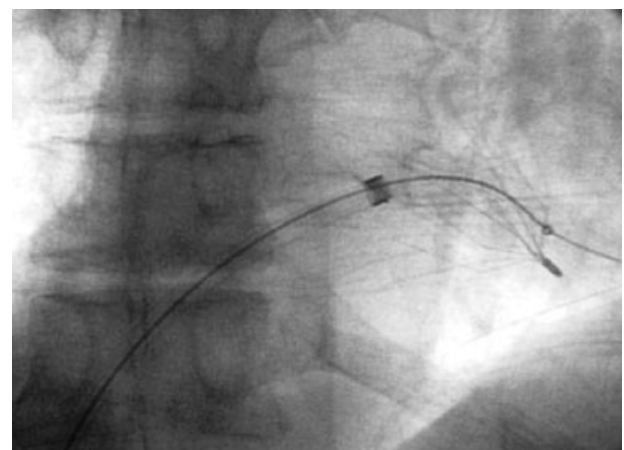
**Insertional problems:** Malfunctions in filter deployment including tilting of the filter more than 15 degrees from the IVC axis, incomplete opening, and prolapse of filter components<sup>6</sup> (► **Fig. 2**).

**IVC perforation:** Visualization of one or more filter components extending greater than 3 mm beyond the caval wall or into an adjacent structure<sup>6</sup> such as the duodenum, aorta, psoas muscle, kidney, or vertebral body. Grading schemes defining the degree of perforation have been described in the literature<sup>7</sup> (► **Fig. 3**).

**Migration:** Movement of an IVC filter greater than 2 cm along the IVC beyond the initial placement position.<sup>6</sup> Filter migration may result in filter embolization into the right atrium, right ventricle, or pulmonary arteries (► **Fig. 4**).



**Fig. 2** Fluoroscopic images showing a severely tilted and tip embedded Celect filter.



**Fig. 4** Fluoroscopic image demonstrating an IVC filter that has migrated into the right ventricle.



**Fig. 5** Coronal CT image showing a Bard filter (open arrow) in place with acute thrombotic occlusion of the IVC (solid arrow).

**IVC occlusion:** Acute or chronic thrombotic occlusion of the IVC following filter placement<sup>6</sup> (► Fig. 5).

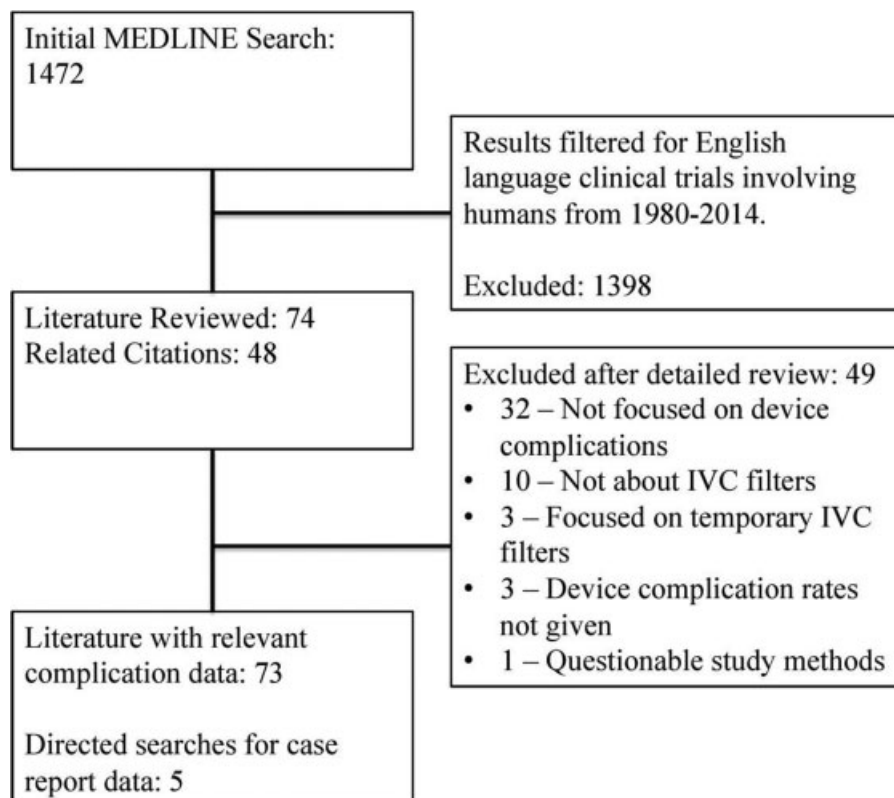
#### Evidence-Based Search of Filter Complications

An electronic MEDLINE search was performed using the following index search terms: “IVC filter” OR “inferior vena cava filter” OR “ALN filter” OR “Bard Eclipse” OR “Bard G2” OR

“Bard G2X” OR “Bard Recovery” OR “Bard Denali” OR “Bard Meridian” OR “Simon Nitinol” OR “Vena Tech LGM” OR “Vena Tech LP” OR “Greenfield filter” OR “Bird’s Nest filter” OR “Celect filter” OR “Günther Tulip” OR “Optease” OR “Trapease” OR “Safeflo” OR “Option filter” OR “Crux vena cava filter.” The results were filtered for English language, clinical trial study type, human species, and date range from 1980 to 2014 (► Fig. 6). All potentially relevant articles were collected for analysis. The references within these articles were reviewed to obtain additional relevant articles for analysis. A data extraction form was used to record the following information: filter type, retrieval rate, complications, and frequency of complications per filter type. Two reviewers verified the accuracy of all data prior to analysis. The FDA Manufacturer and User Facility Device Experience (MAUDE) database<sup>8</sup> was queried electronically (1992–2014) to identify additional adverse events associated with IVC filter use (product class—filter, intravascular, cardiovascular).

#### Results

Twenty-four IVC filters were identified. From this group, the Edwards Mobin-Uddin device was excluded as it was removed from the market in 1986.<sup>9</sup> From the remaining group, nine filters cleared for permanent use, and 14 filters cleared for retrievable or permanent use, were identified (► Table 1). The device distribution based on geometry was as follows: conical ( $n = 15$ ), conical with umbrella ( $n = 1$ ), conical with cylindrical element ( $n = 2$ ), biconical with cylindrical



**Fig. 6** Literature screening flowchart.



**Table 1** IVC Filters in the United States (1980–2014)

Permanent filters	Retrievable filters <sup>a</sup>
<ul style="list-style-type: none"> <li>• 24F stainless steel Greenfield (Boston Scientific, Natick, MA)<sup>b</sup></li> <li>• 12F stainless steel Greenfield (Boston Scientific)</li> <li>• Titanium Greenfield (Boston Scientific)</li> <li>• Vena Tech LGM (B. Braun Medical, Bethlehem, PA)<sup>b</sup></li> <li>• Vena Tech LP (B. Braun Medical)</li> <li>• Trapease (Cordis Endovascular, Warren, NJ)</li> <li>• Bird's Nest (Cook, Bloomington, IN)</li> <li>• Simon Nitinol (Bard Peripheral Vascular, Tempe, AZ)</li> <li>• SafeFlo (Rafael Medical Technologies, Dover, DE)<sup>b</sup></li> </ul>	<ul style="list-style-type: none"> <li>• ALN (ALN International, Miami, FL)</li> <li>• Recovery (Bard Peripheral Vascular)<sup>b</sup></li> <li>• G2 (Bard Peripheral Vascular)<sup>b</sup></li> <li>• G2X (Bard Peripheral Vascular)<sup>b</sup></li> <li>• Eclipse (Bard Peripheral Vascular)<sup>b</sup></li> <li>• Meridian (Bard Peripheral Vascular)<sup>b</sup></li> <li>• Denali (Bard Peripheral Vascular)</li> <li>• Günther Tulip (Cook)</li> <li>• Celect (Cook)<sup>b</sup></li> <li>• Celect Platinum (Cook)</li> <li>• Optease (Cordis Endovascular, Warren, NJ)</li> <li>• Option (Argon, Plano, TX)<sup>b</sup></li> <li>• Option Elite (Argon, Plano, TX)</li> <li>• Crux (Volcano, San Diego, CA)</li> </ul>

<sup>a</sup>All retrievable filters are also approved for permanent use.<sup>b</sup>No longer manufactured but may still be encountered from prior implantation.

element ( $n = 2$ ), helical ( $n = 1$ ), spiral with umbrella ( $n = 1$ ), and complex ( $n = 1$ ) (►Fig. 7).

Reported device-specific complications were identified among all filter types, and the highest reported complications for each device are summarized in ►Table 2. The risk of complications was found to vary widely depending on the specific IVC filter type.

### Fracture

Early conical Bard Peripheral Vascular (Tempe, AZ) filters were associated with the highest reported rates of fracture. The fracture rate for the original Bard Recovery device was 5.5 to 25% with an estimated incidence of 39.5% at 65.7 months.<sup>10–14</sup> The fracture rate for the Bard G2 devices (G2, G2X, Eclipse, Meridian) was initially 1.2 to 12%, but the highest reported rate was later found to be 38% at 60 months.<sup>11,13,15,16</sup> High fracture rates were also reported

for the Simon Nitinol filter (Bard) (10–16%)<sup>17,18</sup> and the Optease/Trapease (Cordis, Miami Lakes, FL) (up to 50%).<sup>19</sup>

### Insertional Issues

Filter tilting greater than 15 degrees during insertion were reported among the following conical filters: Bard Recovery (2.3–15%),<sup>20,21</sup> Bard G2/G2X/Eclipse (14–18%),<sup>15,22,23</sup> Cook (Bloomington, IN) Günther Tulip (11.5–24%),<sup>24–27</sup> 24F Greenfield (Boston Scientific, Marlborough, MA) (7–12%),<sup>28,29</sup> 12F Stainless Steel Greenfield (Boston Scientific) (9.9–55%),<sup>30,31</sup> and Titanium Greenfield (Boston Scientific) (8.3–41%).<sup>30,32,33</sup> In addition, wire prolapse up to 70% was reported for the Cook Bird's Nest filter.<sup>34</sup>

### Inferior Vena Cava Perforation

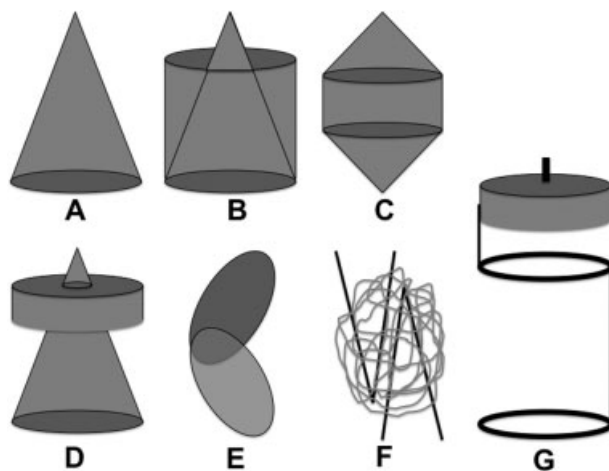
Purely conical filters were associated with the highest reported rates of IVC perforation and were reported as follows: Bard Recovery (27–100%),<sup>12,14</sup> Bard G2/G2X/Eclipse (26–44%),<sup>15,23</sup> Bard Simon Nitinol (25–95%),<sup>17,18</sup> Cook Günther Tulip (22–78%),<sup>7,35–37</sup> Cook Celect (22–93%),<sup>7,35,38,39</sup> and Titanium Greenfield (prior to hook modification) (13–50%).<sup>40,41</sup> In addition, IVC strut perforation up to 85% was reported for the Cook Bird's Nest filter.<sup>34</sup>

### Migration

Migration rates greater or equal to 10% were reported among the following devices: Bard Recovery (0–10%),<sup>10,12,20</sup> Bard G2 (12–25%),<sup>15,20</sup> Titanium Greenfield (7.5–15%),<sup>33,42</sup> Cook Günther Tulip (2.4–12.5%),<sup>26,36,43</sup> and Vena Tech LGM (6–18.4%).<sup>33,44,45</sup>

### Inferior Vena Cava Occlusion

Filters with a cylindrical component (Vena Tech LGM, Trapease/Optease) or umbrella element (Simon-Nitinol) were associated with high rates of caval thrombosis. The highest reported rate of IVC occlusion for the Trapease/Optease filters was 28.6%.<sup>46</sup> The rates of chronic IVC occlusion with the Simon Nitinol filter range from 3.5 to 50%,<sup>17,47–49</sup> and for the VenaTech LGM, the IVC occlusion rate is as high as 65% at 9 years.<sup>45</sup>



**Fig. 7** IVC filter geometries: (A) conical, (B) conical with cylindrical element, (C) biconical with cylindrical element, (D) conical with umbrella, (E) helical, (F) complex, (G) spiral with umbrella.

**Table 2** Highest reported radiographically identifiable complications for each filter type

Device (year FDA cleared)	Fracture	IVC perforation	Migration	IVC occlusion
ALN (2008)	Case reports (0%) <sup>54-56</sup>	3.4% (3.4%) <sup>54</sup>	3% (1.4–3%) <sup>57,58</sup>	Case reports (0%) <sup>54,58,59</sup>
Recovery (2003/2005 <sup>a</sup> )	39.5% at 65.7 mo 25% (5.5–25%) <sup>10-14</sup>	100% (27–100%) <sup>12,14</sup>	10% (0–10%) <sup>10,12,20,21</sup>	Case reports (0%) <sup>14</sup>
G2 (2005/2008 <sup>a</sup> ) G2X (2008) Eclipse (2008) Meridian (2011)	38% at 60 mo 12% (1.2–12%) <sup>11,13,15,16,23,60</sup>	44% (18–44%) <sup>15,23,60,61</sup>	25% (12–25%) <sup>15,20,23</sup>	2.2% (0–2.2%) <sup>22,60</sup>
Denali (2013)	Case reports <sup>62</sup>	2.5% (2.5%) <sup>63</sup>	Limited data	Limited data
Simon Nitinol (1990)	16% (10–16%) <sup>17,18</sup>	95% (25–95%) <sup>17,18</sup>	5% (0–5%) <sup>18,47</sup>	50% (3.5–50%) <sup>17,47-49</sup>
LGM/Vena Tech LGM (1989)	Case reports <sup>64</sup>	Case reports (0%) <sup>44,65</sup>	18.4% (6–18.4%) <sup>33,44,45,66</sup>	65% at 9 y (3.7%) <sup>45</sup>
Vena Tech LP (2001)	Limited data	Case reports (0%) <sup>67</sup>	Case reports (0%) <sup>67</sup>	Limited data
24F SS Greenfield (1973)	Case reports <sup>68</sup>	15% (2–15%) <sup>69,70</sup>	2% (2%) <sup>69</sup>	5% (2–5%) <sup>28,29,71,72</sup>
12F SS Greenfield (1995)	0.3% (0.3%) <sup>73</sup>	1% (1%) <sup>73</sup>	2.6% (2.6%) <sup>73</sup>	12% (5–12%) <sup>31,74</sup>
Titanium Greenfield (1989)	3.8% (3.8%) <sup>74</sup>	50% (13–50% prior to hook modification, 1% with MH design) <sup>40,41</sup>	15% (7.5–15%) <sup>33,42</sup>	20% (3.5–20%) <sup>32,75</sup>
Günther Tulip (2000/2003 <sup>a</sup> )	0.3% (0.3%) <sup>36</sup>	78% (22–78%) <sup>7,35-37</sup>	12.5% (2.4–12.5%) <sup>26,36,43</sup>	4.1% (2.4–4.1%) <sup>36,43</sup>
Celect (2007/2008 <sup>a</sup> ) Celect Platinum (2012)	5.6% (4.3–5.6%) <sup>39,76</sup>	93% (22–93%) <sup>7,35,38,39</sup>	4.3% (0–4.3%) <sup>38,76,77</sup>	2.5% (2.5%) <sup>38</sup>
Bird's Nest (1989)	4% (3–4%) <sup>41</sup>	85% (85%) <sup>34</sup>	1.1% (1.1%) <sup>78</sup>	4.7% (2.9–4.7%) <sup>34,78</sup>
Optease (2002/2004 <sup>a</sup> ) Trapease (2000)	50% (0–50%) <sup>19,79-84</sup>	Case Reports (0%) <sup>79,83,84</sup>	0.9% (0–0.9%) <sup>79-81,83,84</sup>	29% (0.8–29%) <sup>46,79,83,86</sup>
Option (2009)	Limited data	10% (2.9–10%) <sup>37,87</sup>	2% (2%) <sup>87</sup>	4% (4%) <sup>87</sup>
Crux (2012)	Limited data (0%) <sup>88</sup>	Limited data	Limited data (0%) <sup>88</sup>	Limited data (7.2% nonocclusive IVC thrombus) <sup>88</sup>

Abbreviations: FDA, Federal Drug Administration; IVC, inferior vena cava.

Note: For the SafeFlo filter (2009), no significant clinical data are available, and the device is no longer manufactured.

<sup>a</sup>Subsequent year when filter was cleared for retrieval indication.



## Discussion

Over the past few decades, IVC filter use has risen in the United States,<sup>1,2</sup> which has led to increased recognition of a wide range of potential filter-related complications. These complications include fracture, IVC perforation, component embolization, device migration, and IVC occlusion. In response to rising complication rates, the current FDA Safety Alert on IVC filters recommends filter removal when protection from PE is no longer needed. More recently, the FDA released an additional Safety Communication stating that the risk-to-benefit ratio begins to favor IVC filter removal within 29 to 54 days after implantation, if the risk of PE has passed.<sup>50,51</sup>

The systematic review by Angel et al<sup>52</sup> concluded that filter complications are a serious concern associated with long-term filter use, but the study did not address device-specific risks, and there was no analysis specifically of complications from permanent IVC filters. A large variety of retrievable and permanent IVC filters are commonly encountered on routine imaging studies, but the myriad number of filter types and their associated complications prevents interpretation of such radiographic findings. Filter-related complications may therefore go unrecognized or underappreciated as potential causes of morbidity in patients, including those presenting with intractable abdominal pain from filter penetration.<sup>53</sup>

The goal of this study was to evaluate the various FDA-approved IVC filter designs to determine device-specific risks, and to help identify patients who may benefit from ongoing follow-up versus prompt filter retrieval. First, we identified the 23 filter types currently encountered in the United States. Next, the complications associated with each filter type were identified. Although we initially searched the FDA MAUDE database, we soon realized these data were based on voluntary reporting and there was gross underreporting of complications. Therefore, we chose to use evidence-based methods to identify the highest reported complication rates in the literature for each filter type (→ **Table 2**).

These data revealed a high risk of fracture among Bard and Cordis (Miami Lakes, FL) IVC filters, including a fracture incidence of 39.5% at 65.7 months with the Bard Recovery device,<sup>10–14</sup> a 38% risk of fracture at 60 months among the Bard G2 type filters,<sup>11,13,15,16</sup> and a 50% risk of fracture with Cordis Optease/Trapease devices.<sup>19</sup> A high risk of IVC perforation was reported with the Bard Recovery and Cook Celect filters, with penetration rates exceeding 90% for both.<sup>7,12</sup> For permanent filter types, a high risk of IVC occlusion was reported among the Simon Nitinol and Vena Tech LGM,<sup>9</sup> filters with occlusion rates of 50 and 65% (at 9 years),<sup>45,49</sup> respectively. Overall, as these complications appear to be related to filter geometry, one should always assess for IVC perforation, when a conical device is identified, and IVC occlusion, when a cylindrical or umbrella filter component is identified.

This study is limited by the quality of available data on IVC filters, and some filter types in this study were limited published data. In addition, many studies had limited long-term follow-up; therefore, it is possible that the true risk of

complications for these filter types could be even higher than currently reported, as complications tend to increase after longer dwell times. Nevertheless, mitigation against these effects was attempted by identifying the highest complication rates reported so far in the literature. Future studies should involve methods to provide constant updating of filter complication rates as new data emerge in larger cohorts.

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# **EXHIBIT 5**

## **(Filed Under Seal)**

# **EXHIBIT 6**

## **(Filed Under Seal)**